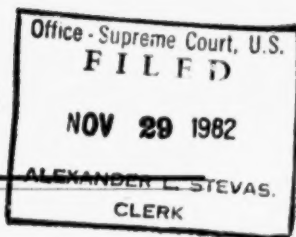


82-909

No.



**In the Supreme Court of the United States**

October Term, 1982

International Rectifier Corporation, Rachelle Laboratories Italia S.p.A., Rachelle Laboratories, Inc. and Rachelle Pharmaceuticals International, S.A.

*Petitioners,*

vs.

Pfizer, Inc.

*Respondent.*

**On Certiorari to the United States Court of Appeals  
For the Ninth Circuit**

**PETITION FOR WRIT OF CERTIORARI**

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**QUESTION PRESENTED**

Is the standard of materiality applied to information to be disclosed to the U.S. Patent and Trademark Office a lower standard than that applied to information to be disclosed to prospective shareholders in securities transactions?

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International Rectifier Corporation, Rachele Labora-  
tories Italia, S.p.A., Rachele Laboratories, Inc., and  
Rachele Pharmaceuticals International, S.A.,

*Petitioners,*

vs.

Pfizer, Inc.,

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**On Certiorari To the United States Court of Appeals  
For the Ninth Circuit**

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**PETITION FOR WRIT OF CERTIORARI**

---

Petitioners International Rectifier Corporation et al., pray  
that a writ of certiorari may be issued to review the opinion and  
judgment of the United States Court of Appeals for the Ninth  
Circuit entered in this case.

**OPINIONS BELOW**

The opinion of the Court of Appeals appears at 685 F.2d  
357, and is printed in the Appendix at A.2. The District Court's  
opinion is reported at 207 USPQ 397 (C.D. Cal. 1980); a  
partial copy appears in the Appendix at page A.5.

## JURISDICTION

The judgment sought to be reviewed was entered on August 26, 1982. Rehearing was denied on September 30, 1982; a copy of the Order denying the petition for rehearing is printed in the Appendix at page A.1. This Court has jurisdiction to review pursuant to 28 U.S.C. Section 1254(1).

## STATEMENT OF THE CASE

Pfizer, Inc. ("Pfizer") brought this action against International Rectifier et al. ("IR") for infringement of its U.S. Patent No. 3,200,149 (the "doxycycline patent").

At trial, IR conceded infringement, asserted invalidity because of obviousness, and asserted a number of specific instances of misrepresentations and withholdings made by Pfizer during the prosecution of the doxycycline patent, in violation of its obligation of candor to the U.S. Patent Office (now the U.S. Patent and Trademark Office, but referred to herein as the "Patent Office").

The doxycycline patent is directed to a class of antibiotics of the tetracycline family and, particularly, to the compound doxycycline (alpha-6-deoxyxytetracycline), and to a process for making doxycycline and certain related compounds. Doxycycline is a widely-used commercial, broad-spectrum antibiotic.

Among the various misrepresentations and withholdings which IR asserted at trial were Pfizer's withholding of information conclusively demonstrating the inactivity of doxycycline against a particular tetracycline-resistant bacterium in living organisms while submitting evidence of favorable test tube results against the same bacterium, Pfizer's withholding of information evidencing its final conclusion that its efforts to employ a ruthenium catalyst in the process claimed for making doxycycline "have failed", and Pfizer's withholding of its final conclusion that its attempts to produce one of the compounds related to doxycycline, viz., 7-chlorodoxycycline, in the claimed process, were "unsuccessful".

The record establishes and the District Court found that Pfizer failed to disclose these facts to the Patent Office. However, the District Court found that Pfizer's withholdings did not amount to fraud or inequitable conduct, because none of its withholdings or misrepresentations was "material".

In its analysis of IR's fraud defense, the District Court determined the materiality of the misrepresented or withheld information under the so-called subjective "but for" test. Under this test, fraud or inequitable conduct before the Patent Office is found only if it can be shown that but for the willful withholding of information from, or but for the willful misrepresentation of information to the Patent Office, the patent would not have been granted.

The Court of Appeals affirmed the lower Court's decision and adopted the District Court's subjective "but for" test, stating:

"... false statements or omissions are material so as to constitute fraud before the Patent Office when such statements or omissions were a "*substantial cause*" of the patent grant or a "*crucial factor*" in obtaining the patent... The proper focus in determining the materiality of the information misrepresented to or withheld from the Patent Office is in the effect of the misrepresentation or withholding upon the subjective considerations of the patent examiner." 685 F.2d at 359; Appendix at A.3.

The Court concluded that the information withheld by Pfizer was not a "crucial factor" or a "substantial cause" of the patent grant, in the light of testimony by a former Patent Examiner that the information withheld "would not have made any difference" in his decision to grant the doxycycline patent. 685 F.2d at 359; Appendix at A.4. Thus, the Court of Appeals did not find that "but for" Pfizer's misrepresentations and withholdings the doxycycline patent would not have been granted. Accordingly, the Court of Appeals held that Pfizer's conduct was not so "material" as to warrant IR's fraud and inequitable conduct defense.



## REASONS FOR GRANTING THE WRIT

### I. THE COURT BELOW IMPOSED A STANDARD OF CANDOR WHICH PROVIDES NO INCENTIVE FOR PATENT APPLICANTS TO DISCLOSE IMPORTANT INFORMATION TO THE PATENT OFFICE AND WHICH FAILS TO PROTECT THE PUBLIC INTEREST IN THE INTEGRITY OF THE PATENT SYSTEM

The constitutional scheme grants to inventors the right to exclude others from making, using and selling their inventions during the lifetime of the patent. The *quid pro quo* underlying the patent grant is therefore the award of a private monopoly in consideration for the disclosure of the invention to the public. Such a private monopoly conflicts with the general hostility of American jurisprudence to monopolies. However, the public policy of encouraging innovation and the disclosure of such innovation to the public has been deemed to outweigh the public policy opposing private monopolies, when the innovation meets the conditions of patentability mandated under Title 35 (the patent code), e.g., novelty, utility and non-obviousness (See 35 USC 101, 102 and 103).

The social and economic consequences of excluding certain products and processes from free and open competition give the public a paramount interest in seeing that patent monopolies do in fact meet the statutory conditions of patentability. When a patent is obtained on subject matter that is not novel or useful or is obvious, and the patent owner then attempts to enforce the patent monopoly, the patent owner not only usurps rights which belong to the public but also undermines the fundamental purpose of the patent laws—to promote innovation. Accordingly, in order to justify the grant of patent monopolies, it is essential that the Patent Office be apprised of all information that may have an important bearing on its decision of whether or not to grant the patent.

Because the Patent Office has no independent testing facilities, it must rely on the patent applicant to disclose important information. Hence, the only way to assure that the

standards of patentability are properly applied and that the resulting private monopolies are limited to their legitimate scope, is to hold the applicant to the highest standards of disclosure and candor and to fashion rules which are designed to assure compliance with those standards.

In accordance with the high degree of public interest which permeates the patent system, this Court in *Precision Instruments Mfg Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806 (1945), imposed an uncompromising duty of disclosure on all patent applicants:

"Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the application in issue . . . Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies." 324 U.S. at 818.

In the present case, however, the Court of Appeals for the Ninth Circuit has applied a standard of materiality which is inconsistent with the uncompromising duty of candor required in *Precision Instruments*. The Court of Appeals' standard requires a court to look at the subjective effect of any misrepresentations or withholdings on the Patent Examiner who considered the application. If the court concludes that the withholding or misrepresentation was a substantial cause or crucial or decisive factor in obtaining the patent—i.e., that "but for" the withholding or misstatement, the patent would not have been granted, then and only then will fraud or inequitable conduct be found. If the withheld or misrepresented information was important to the patentability decision, but would not have been crucial or decisive, no fraud or misconduct will be found.

The "but for" test provides absolutely no inducement for a patent applicant to disclose important information to the Patent

Office. In order to establish "but for" materiality, one must first establish that, if the Patent Office Examiner had considered the withheld or misrepresented information, the Examiner would have decided not to issue the patent on some other independent ground, e.g., lack of novelty or utility, or obviousness. If the Examiner would have refused to issue the patent because of the withheld or misrepresented information, the patent is invalid. But if the applicant had made the disclosure to the Patent Office, then the applicant would not have obtained a patent in the first instance. Thus the patent applicant lost nothing by withholding or misrepresenting the facts.

On the other hand, under the "but for" test, if the withheld or misrepresented information was not crucial and the patent would have issued anyway, then, despite the withholding or misrepresentation, the patent is still valid and enforceable. This is true even if the withheld or misrepresented information would have been important in deciding whether or not the patent should have been granted.

**A. PATENT APPLICANTS SHOULD BE HELD TO THE SAME STANDARD OF CANDOR BEFORE THE PATENT OFFICE AS THAT REQUIRED IN SECURITIES TRANSACTIONS**

The similarity between the standard of candor required of applicants before the United States Patent Office and of those engaged in securities transactions under the jurisdiction of the Securities and Exchange Commission has previously been recognized. In fact, the standards of candor have been equated, both by the Patent Office (see Manual of Patent Examining Procedure Section 2001.05, April 1980 Revision, Appendix, at page A.24), and in *Monsanto Co. v. Rohm & Haas Co.*, 312 F.Supp. 778 (ED Pa. 1970), affirmed 456 F.2d 592 (3d Cir. 1972), cert. denied 407 U.S. 934 (1972), where the Court said:

"The patent applicant should be held to the same standard of truthful disclosure to the Patent Office that

Congress has required of the seller of securities to the public." 312 F.Supp. at 793

In *Monsanto*, the court was confronted with the argument that a patent applicant should not be subject to the same rigorous standards imposed on a dealer in securities. In rejecting this argument, the Court stated:

"Plaintiff argues, however, that the standards of disclosure under the securities act, even if deliberately breached, should not apply to the patent applicant because the purpose of those standards is to prevent the inexperienced investing public from being misled. The Patent Office, on the other hand, has the expertise necessary to decide whether to issue a patent without requiring complete scientific candor from patent applicants. We find this argument to be without merit for two reasons. First, the public does have an interest in seeing that 17 year monopolies are not given without a full and complete airing of all relevant facts. This public interest cannot be diminished by the fact that it is not as directly involved in the patent process as the investing public is in the process of the sale of a security. Second, the Patent Office cannot possibly have a detailed technical expertise in every scientific area without relying to some degree on the scientific candor of patent applicants. It cannot be expected to perform tests and experiments to determine whether an applicant's alleged invention is in fact an invention. Further, since patent application proceedings are not ordinarily adversary proceedings, the Patent Office must rely on the tests and experiments and good faith of the applicant." 312 F.Supp. at 793.

The definition of materiality promulgated by the Ninth Circuit is, however, in direct conflict with the definition of materiality defined by this Court for securities transactions in *TSC Industries v. Northway*, 426 U.S. 438 (1976). The *TSC Industries* case concerns omissions and misstatements made in connection with Section 14(a) of the Securities and Exchange Act of 1934 and Rules 14(a)-9 and 14(a)-3 promulgated by the Securities and Exchange Commission, dealing with proxy

solicitation. In *TSC*, this Court specifically rejected a definition in which omitted or misstated information must be *decisive* to be material. Instead the court held that for the omitted or misstated information to be material it must only be important, stating:

“The general standard of materiality that we think best comports with the policies of Rule 14a-9 is as follows: an omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it *important* in deciding how to vote. . . . It does not require proof of a substantial likelihood that disclosure of the omitted fact would have caused the reasonable investor to change his vote. What the standard does contemplate is a showing of a substantial likelihood that, under all the circumstances, the omitted fact would have assumed *actual significance* in the deliberations of the reasonable shareholder. Put another way, there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” 426 U.S. at 449; (emphasis added).

Thus, we are confronted with an anomaly. In a securities transaction among private parties any information which would be *important* to reasonable shareholders or investors must be disclosed. On the other hand, in transactions before the Patent Office, transactions which result in the granting of private monopolies by removing selected products and processes from the competitive market place, the Court of Appeals for the Ninth Circuit has imposed a much lower standard of disclosure.

There is no basis in logic or policy for such a distinction, especially in this case which involves a widely used, commercial antibiotic. Clearly, it is in society's interest to have this type of drug available at the lowest price possible. This interest should be thwarted only by a patent granted after complete consideration of all known important information.

The societal interest in preventing fraud in securities transactions is certainly no greater than the societal interest in

preventing fraud in the granting of patents. If anything, that interest in the integrity of the patent system is greater, because of the private, monopolistic nature of patent grants. Surely, a prospective licensee of a patent, i.e., a potential investor in a patent, should have the same level of confidence that a patent is not tainted with fraud that a prospective investor in a company owning that patent has in a stock, bond, or other security of that company. Surely, conduct which would be penalized in a securities transaction should not be rewarded by the grant of a patent.

The subjective "but for" test applied by the Court of Appeals in this case is likely to be applied throughout the federal courts in future proceedings. Under P.L. 97-164 the new Court of Appeals for the Federal Circuit (the "CAFC") now has exclusive jurisdiction over all patent appeals from the District Courts. The Courts of Appeals for the various circuits will no longer decide patent appeals. In *South Corp. v. U.S.*,

433 F.2d 779 (CAFC 1982), the first published opinion by the CAFC, the CAFC declared that the holdings of its predecessor courts will be binding on it as precedent. The Court of Customs and Patent Appeals (the "CCPA"), one of the CAFC's predecessor courts, has, however, previously applied the same subjective "but for" test followed by the Ninth Circuit in the case at bar,<sup>1</sup> *Norton v. Curtiss*, 433 F.2d 779 (CCPA, 1970); and *Langer & Tornquist v. Kaufman & McMullen*, 465 F.2d 915 (CCPA 1972). It is thus incumbent on this Court to review the "but for" rule espoused by the Court of Appeals in the present case, and by the CCPA, in order to avoid perpetuating a rule in *all* federal courts which may compromise the very integrity of the patent system.

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<sup>1</sup> In fact, the Court of Appeals relied on the *Norton* rule in reaching its decision herein. 685 F.2d at 359.

## **II. GUIDANCE FROM THIS COURT IS NECESSARY TO CORRECT THE HOPELESS CONFUSION IN PRIOR DETERMINATIONS AS TO THE MATERIALITY OF WITHHOLDINGS AND MISREPRESENTATIONS BEFORE THE PATENT OFFICE**

Apart from the compelling public policy considerations advanced above, guidance from this Court is necessary to resolve the utter chaos in the lower courts and the Patent Office respecting the determination of the materiality of information withheld from or misrepresented to the Patent Office during patent prosecution.

First, contrary to the Court of Appeals in this case, the Patent Office Rules (37 CFR 1.56(a), Appendix at page A.23) define material information as information "where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." This is a paraphrase of the Supreme Court definition of materiality in *TSC Industries, supra* (Manual of Patent Examining Procedure, Section 2001.05, Appendix at page A.24). Thus, there is a conflict between the Patent Office Rule and the "but for" test of the *Norton* precedent adopted in this case and most likely to be made binding on all the District Courts by the CAFC.

Second, the wide diversity in the test for materiality heretofore adopted by the various Courts of Appeals and District Courts establishes a need for a definition of the materiality standard by this Court. Some courts have adopted a test known as the objective "but for" test wherein if the court concludes that the invention was objectively patentable under the full and accurate factual circumstances, then any withholding or misrepresentation is not deemed material.<sup>2</sup>

The objective "but for" test is to be contrasted with the subjective "but for" test adopted by the Court of Appeals in the present case. This test requires a court to examine the

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<sup>2</sup> *Feed Service Corp v. Kent Feeds Inc.*, 528 F.2d 756, (7th Cir. 1976); *Wen Products Inc. v. Portable Electric Tools Inc.*, 367 F.2d 764, (7th Cir. 1966).

subjective effect which fraudulent representations had upon the Patent Office Examiner. If "but for" the misrepresentations or withholdings the Examiner would not have issued the patent, then the misrepresentations or withholdings are material.<sup>3</sup> Neither of these "but for" tests provides the slightest incentive for full disclosure by patent applicants.

Still other courts have adopted definitions of materiality similar to the Patent Office test. Such courts impose on patent applicants the obligation to disclose not only those facts "but for" the withholding or misrepresentation of which the resulting patent would not have been granted, but those additional facts which may be relevant to or important in the determination of patentability.<sup>4</sup>

The diverse and conflicting views of the federal trial and appellate courts, and the federal agency charged with administering the patent system, call out to this Court for further guidance as to the correct "materiality" standard to be applied in determining the scope of the obligation of candor imposed upon all applicants for patent.

<sup>3</sup> *Eudy v. Motor-Guide, Herschede Hall Clock Co.*, 651 F.2d 299, 305 (5th Cir. 1981); *Clark Equipment Co. v. Keller*, 570 F.2d 778, 790 (8th Cir. 1978), cert. denied, 439 U.S. 825 (1978).

<sup>4</sup> *Timely Products Corporation, et al v. Aaron et al*, 523 F.2d 288, 298 (2d Cir. 1975); *In re Multidistrict Litigation Involving Frost Patent*, 540 F.2d 601, 604 (3d Cir. 1976): "An omission or misrepresentation is material if it makes it 'impossible for the Patent Office fairly to assess [the patent] application against the prevailing statutory criteria.'"; and *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 600 (3d Cir. 1972), cert. denied, 407 U.S. 934 (1972); *Duplan v. Deering Milliken Corp.*, 444 F.Supp. 648, 732 (D.C.S.C. 1977), rev'd in part on other grounds, 594 F.2d 979 (4th Cir. 1979), cert. denied, 444 U.S. 1015 (1980); *True Temper Corp. v. C F&I Steel Corp.*, 601 F. 2d 495, 504 (10th Cir. 1979): "The withheld information was material in that it was relevant and clearly significant to the consideration of the application by the Patent Office".



## CONCLUSION

For the reasons stated above, the subjective "but for" test of materiality adopted by the Court of Appeals for the Ninth Circuit in the present case does not adequately protect the societal interest in the integrity of the patent system. Accordingly, a writ of *certiorari* should be granted for the purpose of determining the proper test to be applied respecting the materiality of misrepresentations and withholdings of information relied upon as evidence of fraud or inequitable conduct in defense of patent infringement proceedings.

Respectfully submitted,

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